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Update on Japan's Biotechnology Safety Approval and Labeling Policies

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Report Highlights: Japan has approved 37 biotech varieties through its ongoing safety assessment process. New legislation went into effect on April 1 which made it illegal to import biotech varieties which have not been approved in Japan for food use. The Japanese government has begun testing import shipments to make sure they do not contain unapproved biotech varieties. Food products containing approved biotech varieties must be so labeled, if the biotech ingredients are scientifically detectable.

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Executive Summary

Japan's Ministry of Health, Labor and Welfare (MHLW) is responsible for granting food safety approvals for biotech products. As of August 2001, MHLW had approved 37 biotech varieties for food use. New legislation which went into effect on April 1 made it illegal to import products for food use which contain biotech varieties which are not yet approved in Japan. To enforce this legislation, MHLW began a sampling and testing program for imported foodstuffs at ports of entry. Their testing has focused on biotech products which are in commercial production abroad, but not yet approved in Japan. Foods found to contain unapproved biotech varieties must be re-exported, destroyed or diverted to non-food use. Since April, MHLW has found only one unapproved biotech variety of potatoes as a result of both this testing, and ongoing testing of finished food products by local governments.

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for environmental safety approvals, feed safety approvals and biotech labeling for foods. On April 1, 2001, MAFF established a labeling scheme which requires labeling for biotech food products if the biotech DNA or protein can be scientifically detected in the finished foods. Biotech advisory labels for the 24 products covered under this program are mandatory if the biotech content exceeds 5%. MHLW also plays a role in enforcing labeling standards under the Food Sanitation Law, but their standards are exactly the same as MAFF's Japan Agricultural Standards. In order for a product to be labeled "Non-GM", certification must be provided to show that the ingredients were handled on an "identity-preserved" (IP) basis at each step of the production and distribution process. To date, MAFF has checked 59 products and found one product, corn grits, which was improperly labeled because it did not show that it was made using "GM Ingredients" when the biotech content exceeded the Government's informal 5% tolerance.

For more information on the market impact of Japan's labeling and monitoring policies, please refer to FAS/Japan's reports on-line at <http://www.fas.usda.gov>.

Safety Assessment Procedures for Products of Biotechnology

The Ministry of Health, Labor and Welfare administers scientific reviews to assess the safety of new biotech varieties. Life sciences companies must first submit their application for safety approval to MHLW's Inspection and Safety Division to make sure that their application is properly prepared. MHLW then submits the application to the Expert Panel, of the Biotechnology Subcommittee, of the Food Sanitation Committee. The Expert Panel reviews the application and makes a recommendation with regard to approval to the Biotechnology Subcommittee, which in turn provides its judgement to the Food Sanitation Committee. The Food Sanitation Committee then makes the final decision on whether or not to recommend approval to MHLW's Minister, and if it is approved it is published in the Japanese Government's "Gazette", which is similar to the Federal Register. For MHLW's most recent list of approved biotechnology traits, browse their summary on the Internet at <http://www.mhlw.go.jp/english/topics/food/sec01.html>.

The Ministry of Agriculture Forestry and Fisheries administers environmental safety assessments

and feed safety assessments for biotech products. MAFF's environmental safety assessment is voluntary, but virtually all biotech developers submit applications to have new varieties approved, either for importation or for cultivation in Japan. For varieties which will be either imported or cultivated in Japan, developers must obtain approval for field testing, which then must then be done in Japan by the Japanese government.

MAFF is also responsible for approving new biotech varieties for feed use and for a marketing program which includes a voluntary feed safety assessment. Under MAFF's approval process the application for approval is reviewed by the Experts Committee of the Agricultural Materials Council, after it has been reviewed by the MAFF's Feed Division to make sure that it has been properly prepared. The Council then reviews the application and makes its recommendation to MAFF's Minister on whether or not to approve the variety for feed use.

The following list of biotech traits have been approved in Japan for the specific purposes listed below.

List of Currently Approved Biotechnology Products in Japan (as of August 2001)

Plant species	Developer	Characteristics	Import	Planting	Feed	Food
Tomato	Nat'l Agr. Ctr.	Virus resistant	1992	1992	-	-
Petunia	Suntory	Virus resistant	1994	1994	N/A	N/A
Rice (Nipponbare16-2)	Nat'l Agr. Ctr.	Virus resistant	1994	1994	-	-
Rice (Kinuhikari)	Plant Tech. Ctr	Virus resistant	1994	1994	-	-
Melon	Nat'l Agr. Ctr.	Virus resistant	1996	1996	-	-
Rice (Kinuhikari)	Mitsui Chemicals	Low allergenicity	1995	1995	-	-
Soybean (40-3-2)	Monsanto	Herbicide tolerant	1996	1996	1996	2001
Tomato (405, 407)	Nat'l Veg. Res.	Virus resistant	1996	1996	-	-
Canola (RT73)	Monsanto	Herbicide tolerant	1996	1996	1996	2001
Tomato (ICI9, ICI13)	Zeneca/Kagome	High pectin	1996	1996	-	-
Tomato	Calgene	High pectin (long life)	1996	1996	-	-
Carnation (A-127)	DNAP/Suntory	Long life	1996	1996	N/A	N/A
Canola (HCN92)	AgrEvo	Herbicide tolerant	1996	-	1996	2001
Canola (HCN10)	AgrEvo	Herbicide tolerant	1997	-	1998	2001
Canola (PGS1)	Plant Genetic Systems (PGS)	Herbicide tolerant	1996	-	1996	2001
Canola (PHY14)	PGS	Herbicide tolerant	1997	-	1998	2001

Canola (PHY35)	PGS	Herbicide tolerant	1997	-	1998	2001
Canola (T45)	AgrEvo	Herbicide tolerant	1997	-	1997	2001
Corn (T-14)	AgrEvo	Herbicide tolerant	1997	-	1997	2001
Corn (T-25)	AgrEvo	Herbicide tolerant	1997	-	1997	2001
Corn (MON810)	Monsanto	Insect resistant	1996	-	1997	2001
Corn (MON802)	Monsanto	Insect resistant, herbicide tolerant	1997	-	-	-
Tomato (117,1946,1204,1208)	Nat'l Veg. Res.	Virus resistant	1997	1997	-	-
Corn (Bt11)	Northlap King	Insect resistant	1996	-	1996	2001
Corn (Event176)	Ciba Seed	Insect resistant	1996	-	1996	2001
Canola (PGS2)	PGS	Herbicide tolerant, male sterile, sterility recovery	1997	-	1997	2001
Canola (PHY36)	PGS	Herbicide tolerant, male sterile, sterility recovery	1997	-	1997	2001
Canola (PHY23)	PGS	Herbicide tolerant, male sterile, sterility recovery	1997	-	1999	2001
Corn (DLL25-DK566)	Dekalb	Herbicide tolerant	1997	1997	-	-
Corn (DBT418-DK566)	Dekalb	Insect resistant, herbicide tolerant	1997	1997	-	-
Cotton (531)	Monsanto	Insect resistant	1999	-	1997	2001
Cotton (757)	Monsanto	Insect resistant	1999	-	1997	2001
Rice (Nipponbare: 20-2, 21-3)	Nat'l Agr. Res. Ctr.	Virus resistant	1997	1997	-	-
Potato (Bt6)	Monsanto	Insect resistant	Not needed	Not needed	N/A	2001
Potato (SPBT02-05)	Monsanto	Insect resistant	Not needed	Not needed	N/A	2001
Carnation (2, 11)	Florigene/Suntory	Color change	1997	1997	N/A	N/A
Corn (MON809)	Monsanto	Herbicide tolerant	1997	-	1998	-
Canola (Westar-Oxy-235)	Rhone Poulanc	Herbicide tolerant	1998	-	1999	2001

Canola (MS8RF3)	PGS	Herbicide tolerant, male sterile, sterility recovery	1998	-	1998	2001
Corn (CBH351)	PGS	Insect resistant, herbicide tolerant	1999	-	-	-
Cotton (1445)	Monsanto	Herbicide tolerant	1997	-	1998	2001
Cotton (10211)	Monsanto	Herbicide tolerant	1997	-	-	2001
Cotton (10215)	Monsanto	Herbicide tolerant	1997	-	1998	2001
Cotton (10222)	Monsanto	Herbicide tolerant	1997	-	1998	2001
Cotton (10224)	Monsanto	Herbicide tolerant	1997	-	1998	-
Rice (H39, H75)	Japan Tobacco	Low protein	1998	1998	-	-
Carnation (1351, 1363)	Florigene/Suntory	Color change	1998	1998	N/A	N/A
Corn (GA21)	Monsanto	Herbicide tolerant	1998	1998	1999	2001
Corn (DLL25)	Dekalb	Herbicide tolerant	1999	-	2000	2001
Corn (DBT418)	Dekalb	Insect resistant, herbicide tolerant	1999	-	2000	2001
Soybean (260-05)	DuPont	High oleic acid	1999	-	2000	2001
Soybean (A2704-12)	AgrEvo	Herbicide tolerant	1999	-	-	-
Cotton (31807)	Monsanto	Insect resistant, herbicide tolerant	1998	-	1999	-
Cotton (BG4740)	Monsanto	Insect resistant, herbicide tolerant	1998	-	-	-
Azuki bean (AR-9)	Nat'l Agr. Res. Ctr.	Insect resistant	1999	1999	-	-
Cucumber (CR-29, 32, 33)	Nat'l Agr. Res. Ctr.	Disease resistant	1999	1999	-	-
Tomato (4-7)	Hokkaido Agr. Station	Virus resistant	2000	2000	-	-
Trenia (1165, 1382)	Florigene/Suntory	Color change	1998	1998	N/A	N/A
Canola (MS8)	PGS	Herbicide tolerant, male sterile	-	-	1999	2001
Canola (RF3)	PGS	Herbicide tolerant, sterility recovery	-	-	1999	2001

Carnation (121.2.7, 121.3.12, 123.1.36,123.2.38)	Florigene/Suntory	Color change	1999	1999	N/A	N/A
Carnation (8.6.25, 12.1.8, 17.3.67, 18.3.33, 20.9.53)	Florigene/Suntory	Long life	1999	1999	N/A	N/A
Rice (KA130)	Orynova	Low glutenin	2000	2000	-	-
Rice (LLRICE62)	AgrEvo	Herbicide tolerant	2000	-	-	-
Rice (730, 1107, 1316, 1702, 1708, 1763)	Monsanto	Herbicide tolerant	2000	2000	-	-
Sugar beet (T120- 7)	AgrEvo	Herbicide tolerant	Not needed	Not needed	1999	2001
Carnation (123.8.8)	Suntory	Color change	2000	2000	N/A	N/A
Carnation (1.8.124, 16.0.66)	Suntory	Low ethylene production	2000	2000	N/A	N/A
Papaya (55-1)	Mac (Cornel University)	Ringspot Virus resistant	2000	-	-	-
Corn (NK603)	Monsanto	Herbicide tolerant	2001	2001	-	2001
Sweet corn (Bt11)	Novartis		-	-	-	2001
Cauliflower (CF156)	Takii Shubyo	Male sterile and herbicide tolerant	-	2001	-	-
Broccoli (BR891)	Takii Shubyo	Male sterile and herbicide tolerant	-	2001	-	-
Corn (MON863)	Monsanto	Insect resistant	2001	-	-	-
Rice (G2-59, G2- 70, G2-138)	Aich Prefecture Ag Station, Monsanto	Herbicide tolerant	-	2001	-	-
Cotton (15985)	Monsanto	Insect resistant	2001	-	-	-
Potato (New Leaf Plus: RBMT21- 129, RBMT21- 350, RBMT22- 082)	Monsanto	Insect resistant and virus resistant	Not needed	Not needed	N/A	2001
Canola (RT200)	Monsanto	Herbicide tolerant	-	-	-	2001
Total numbers			Import	Planting	Feed	Food
			65	34	33	37

Year's indicate the year in which specific uses were approved. '-' indicates the safety has not been confirmed by the Government of Japan. Potatoes and sugar beets are imported to Japan only in processed foods, thus no approval

is required for importation and planting. 'N/A' means not applicable.

Labeling Policy for Biotech Products

For biotech products which have been approved in Japan, MAFF and MHLW implemented labeling requirements under the Food Sanitation Law and the Japan Agricultural Standards (JAS) Law, respectively. Although both Ministries have labeling requirements, both sets of requirements are exactly the same. To view MAFF's labeling policy on biotechnology traits, see their Internet site at http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf.

In order to be labeled "Non-GM" the biotech content of foods must be less than 5%, and the processor must be able to show that all biotech ingredients were handled on an "identity-preserved" (IP) basis from production through processing. The English version of the manual for the IP handling is available at the Japan Food Industry Center's website (http://www.shokusan.jp/business/pdf/ip_manul.pdf). Special labeling requirements apply to 24 kinds of food made from corn and soybeans. If the biotech content of these 24 foods exceeds 5 percent, they must be labeled either "GM Ingredients Used" or "GM Ingredient Not Segregated." (see GAINS report JA9154 for more information)

The 24 foods currently subject to JAS labeling requirements were selected because they are made from ingredients which could include the products of biotechnology, and because it is possible to detect the genetically-introduced DNA or protein in the foods. If companies want to label their products as being "Non-GM", they must also provide certification to show that proper IP handling procedures were followed. Responsibility for this certification lies with suppliers in the United States and other countries, and not with Japan's food importers or manufacturers.

MAFF and MHLW periodically revise their list of foods subject to monitoring and labeling as new biotech varieties go into production and new detection methodologies are developed.

Monitoring of GM or Non-GM Labeled Foods

MAFF and MHLW both randomly monitor samples of the 24 foods which are currently under the labeling program for biotech ingredients. The Japanese Government's recognizes that even though proper IP handling and distribution methods are used, a possibility exists for adventitious commingling of biotech products in non-GM products. They have therefore set an informal tolerance of 5% for biotech ingredients in products which are labeled "Non-GM." This tolerance only applies to varieties which have been approved in Japan. If officials find products labeled "Non-GM" which have a biotech content of over 5 %, the ministry which identified the problem issues guidance directing the food manufacturer or importer to correct the product's label to show that it was made with "Genetically Modified Ingredients."

MAFF's Consumer Technology Center recently announced that it sampled 59 food items to check their compliance with the new GM labeling requirements. Their investigation, which included DNA analysis and a review of paperwork to assure proper IP handling of ingredients, shows how MAFF is assuring compliance with its new regulations. The items sampled included foods subject to the JAS GM labeling requirements which were either labeled "Non-GM" (34

items) or had no labeling with respect to biotech content (25 items). First a qualitative DNA analysis was performed on the food samples to see if they contained any level of biotech ingredients. The foods in which DNA was detected were then further analyzed with a quantitative PCR test, and their paperwork was reviewed to assure proper IP handling procedures had been followed. The qualitative DNA analysis detected biotech ingredients in 11 of the 59 samples. These samples were then retested with a quantitative testing procedure.

In one sample the level of GM-derived DNA exceeded the informal threshold for unintentional commingling of 5%. The Consumer Technology Center issued guidance to the manufacturer of the item directing them to correct the labeling to show that the product was made with "GM Ingredients". The company was also directed to make sure that they have appropriate IP handling procedures. The manufacturer reportedly voluntarily recalled the product on the same day.

The content of the GM-derived DNA in the other four food samples was below 5%. For six food samples which contained biotech varieties for which a quantitative DNA analysis method has not been established, proper IP handling was confirmed and it was determined that those products were adequately labeled.

Item		No of samples	GM-derived DNA detection		Quantitative DNA analysis
			Not detected	Detected	
	Soybean	3	3	0	
Processed foods of soybean	Tofu	10	8	2	No accurate quantitative DNA analysis method is available for foods for the six positive samples.
	Fried tofu	10	8	2	
	Kori tofu	3	2	1	
	Soybean refuse	5	5	0	
	Yuba	3	2	1	
	Natto	3	3	0	
	Miso	3	3	0	
	Cooked soybean	3	3	0	
	Roasted soybean flour	4	4	0	
	Corn snack	7	7	0	

	Corn grits	4	0	4	One item contained about 6%. Other three was below 5%.
	Foods mainly made from corn flour	1	0	1	Below 5%
	Total	59	48	11	

Monitoring for Unapproved Biotech Varieties in Foods

Like the United States, Japan has a zero tolerance for unapproved biotech varieties in foods. To assure compliance, a sampling program is in place to test both import shipments and processed food products at the retail level. Any detection of an unapproved biotech variety in a food is deemed a violation of Japan's Food Sanitation Law. Testing at ports is handled by MHLW directly, while local health authorities handle testing for processed foods at the retail level. All testing is performed using sampling and testing plans prepared by MHLW. If the detection is at the port, the shipment must be re-exported, destroyed or diverted for non-food use. If the detection is at the retail level, the manufacturer of the product must issue an immediate recall. The main products currently being tested are soybeans, corn, papayas, and potatoes. Since the new law was implemented on April 1, the testing programs at ports and for finished products have resulted in only one actual finding of an unapproved biotech variety. The product involved was a potato snack which contained a small amount of New Leaf Plus potatoes, a variety which has been approved in the United States and Canada, but not in Japan.

A MAFF advisory board recently recommended that Japan set a 1% tolerance for animal feed for biotech varieties which are approved in other OECD countries, but not yet approved in Japan. However, it is not yet clear if this recommendation will be adopted.